Responsive QA: Final Guidance #236 – *Clarification of FDA and EPA Jurisdiction over Mosquito-Related Products*

October XX, 2017

NEW – *Q. How does the final guidance differ from the draft guidance?*

Ex. 5 - Deliberative Process

NEW – Q. Does FDA currently have an EA from Oxitec for a proposed field trial in a different location or an application for commercial approval? Is FDA currently reviewing any other mosquito products in the pipeline?

Ex. 5 - Deliberative Process

NEW – *Q. When will the FDA finalize GFI #187?*

Ex. 5 - Deliberative Process

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Q. What does this guidance say about how FDA regulates mosquito-related products?

Ex. 5 - Deliberative Process

Q. Does this guidance apply to insects, more generally?

Ex. 5 - Deliberative Process

Q. What does this mean for the Oxitec mosquito?

Ex. 5 - Deliberative Process

Q. What if a company decided to pursue a dual claim consisting of both a disease and population-control claim?

Ex. 5 - Deliberative Process

Q. Why was the FDA regulating the Oxitec mosquito, when its intent was to reduce the Aedes aegypti mosquito population?

Ex. 5 - Deliberative Process

Q. Will Oxitec need to go through further EPA regulation if it is transferring agencies?

Ex. 5 - Deliberative Process

Q. What does this mean for Oxitec's proposed field trial in Florida?

A. The FDA has been and, as needed, will continue to work with EPA to facilitate a smooth transition of regulatory jurisdiction over Oxitec's OX513A mosquitoes that are intended to suppress the wild-type *Ae. aegypti* mosquito population in areas where they are released.

Questions about next steps should be directed to Oxitec.